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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Note to Reader
January 15, 1998

Background: As part of its effort to involve the public in the implementation of the Food Quality Protection Act of 1996 (FQPA), which is designed to ensure that the United States continues to have the safest and most abundant food supply. EPA is undertaking an effort to open public dockets on the organophosphate pesticides. These dockets will make available to all interested parties documents that were developed as part of the U.S. Environmental Protection Agency's process for making reregistration eligibility decisions and tolerance reassessments consistent with FQPA. The dockets include preliminary health assessments and, where available, ecological risk assessments conducted by EPA, rebuttals or corrections to the risk assessments submitted by chemical registrants, and the Agency's response to the registrants' submissions.

The analyses contained in this docket are preliminary in nature and represent the information available to EPA at the time they were prepared. Additional information may have been submitted to EPA which has not yet been incorporated into these analyses, and registrants or others may be developing relevant information. It's common and appropriate that new information and analyses will be used to revise and refine the evaluations contained in these dockets to make them more comprehensive and realistic. The Agency cautions against premature conclusions based on these preliminary assessments and against any use of information contained in these documents out of their full context. Throughout this process, If unacceptable risks are identified, EPA will act to reduce or eliminate the risks.

There is a 60 day comment period in which the public and all interested parties are invited to submit comments on the information in this docket. Comments should directly relate to this organophosphate and to the information and issues available in the information docket. Once the comment period closes, EPA will review all comments and revise the risk assessments, as necessary.

These preliminary risk assessments represent an early stage in the process by which EPA is evaluating the regulatory requirements applicable to existing pesticides. Through this opportunity for notice and comment, the Agency hopes to advance the openness and scientific soundness underpinning its decisions. This process is designed to assure that America continues to enjoy the safest and most abundant food supply. Through implementation of EPA's tolerance reassessment program under the Food Quality Protection Act, the food supply will become even safer. Leading health experts recommend that all people eat a wide variety of foods, including at least five servings of fruits and vegetables a day.

Note: This sheet is provided to help the reader understand how refined and developed the pesticide file is as of the date prepared, what if any changes have occurred recently, and what new information, if any, is expected to be included in the analysis before decisions are made. **It is not meant to be a summary of all current information regarding the chemical.** Rather, the sheet provides some context to better understand the substantive material in the docket (RED chapters, registrant rebuttals, Agency responses to rebuttals, etc.) for this pesticide.

Further, in some cases, differences may be noted between the RED chapters and the Agency's comprehensive reports on the hazard identification information and safety factors for all organophosphates. In these cases, information in the comprehensive reports is the most current and will, barring the submission of more data that the Agency finds useful, be used in the risk assessments.

Jack E. Housenger, Acting Director
Special Review and Reregistration Division

PROPETAMPHOS
ERRATA SHEET FOR EFED CHAPTER

The Registrant provided three comments on the EFED Integrated Science Chapter for Propentamphos. The first comment was about label language recommended in the EFED Chapter. The Registrant has agreed to make the change to the label for Registration number 2724-450 to include the language "for indoor use only." The label should be revised to read as follows:

" FOR INDOOR USE ONLY. Permitted sites of application include inside homes, apartments, buildings, stores, schools, nursing homes, hospitals, industrial buildings and warehouses (excluding food and feed warehouses) but not including any areas in which food processing, packing and food and/or feed warehousing occurs. The products may be used in food service establishments such as structures/area listed under the Food Service Establishments section of the label."

The revised label language will be incorporated into the final RED and will be required as a condition of Reregistration for all registered end use products (i.e., 2724-449 and 2724-450).

The second comment was about the end use formulations of propetamphos that are currently registered for use in the United States. The comment reads as follows:

> "Four end use formulations, three emulsifiable concentrates (18.9%, 46.5% and 50.0%) and one pressurized liquid formulation are identified for propetamphos. In fact only the 18.9% formulation [2724-449] is currently manufactured. The 46.5% EC [2724-449] was manufactured for export only and has never been sold in the US. The 50 % EC [2724-314] and the 1% pressurized liquid [2724-340] were canceled in July 1998."

The Agency erroneously included the 50 % EC [EPA Registration Number 2724-314] and the 1% pressurized liquid [EPA Registration Number 2724-340] in the ecological risk assessment. These formulations will be deleted from the revised risk assessment document.

The most recent EPA approved label for the 46.5% EC [EPA Registration Number 2724-449] does not specify "for export only." Therefore, both the 46.5% EC and the 18.9% formulation [2724-449] will be included in the risk assessment until such a time when the label for the 46.5% formulation is modified to specify that manufacture is for export only.

Last, the Registrant claimed that the annual use rates given in the ecological risk assessment is an overestimate. The Agency is investigating this claim. The Registrant also contends that the total annual use rate should be considered CBI. All information claimed CBI will be deleted from the document available in the public docket.

MEMORANDUM

SUBJECT: EFED Science Chapter for the Propetamphos Reregistration Eligibility Document (Chemical #113601, DP Barcode D237915)

FROM: William Evans, Biologist, Task Leader
Ecological Hazard Branch

James Goodyear, Ph. D., Biologist
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Kevin Poff, Chemist
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THRU: Thomas Bailey, Ph.D., Chief
Ecological Hazards Branch
Environmental Fate and Effects Division (7507C)

Elizabeth Behl, Chief
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TO: Walter Waldrop, Chief
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Special Review and Reregistration Division (7508W)

Attached please find the Environmental Fate and Effects Division Integrated Science Chapter for propetamphos. The risk analysis considers the use of propetamphos as an acaricide-Insecticide for Indoor Food, Indoor Non-food, Indoor Medical, Indoor residential use sites.

Assessment Summary

Environmental Fate

The EFED has extremely limited data on the chemical propetamphos as the uses are limited to indoor use only. Generally, for indoor use chemicals, only hydrolysis data are required. The available data indicate propetamphos is stable to hydrolysis at neutral pH and hydrolyses under acidic (pH 3) and alkaline (pH 9) conditions slowly with half-lives of 11 and 41 days respectively. Propetamphos is soluble in most organic solvents, has a water solubility of 110 ppm at 24^{o}C and has a boiling point of 0.005 mm Hg at 87-89 C.

Water Resources

Due to the use of propetamphos being limited to indoor use only, environmental exposure is considered to be negligible.

Ecological Effects

Because all currently registered products of Propetamphos are limited to indoor uses, little exposure to nontarget terrestrial organisms is expected. In addition, little exposure from spray drift or run-off to aquatic ecosystems is expected. For this reason, the EFED does not conduct a hazard assessment or risk characterization.

Propetamphos is categorized as moderately toxic to avian species on an acute oral basis (LD50 = 197mg/kg) and highly toxic on a subacute dietary basis (LC50 = 258 ppm). the LC50 falls in the range of 188 to 2600 ppb, Propetamphos is categorized as highly toxic to freshwater fish (LC50 = 188 ppb) and very highly toxic to aquatic invertebrates on an acute basis (3.3 - 14.5 ppb).

Status of Data Requirements

Environmental Fate

Since all registered products of propetamphos are restricted to indoor uses the only environmental fate data that are required is a hydrolysis study. As this study has been submitted and validated all environmental fate data requirements are fulfilled.

Ecological Effects

To establish toxicity levels for products limited to indoor uses the EFED requires acute testing of an avian species, preferably the bobwhite quail. The required tests include an acute oral LD50 and a dietary LC50. For aquatic species, the EFED requires acute testing of a freshwater fish species and a freshwater aquatic invertebrate.

All required ecological effect data are currently fulfilled for propetmaphos for products limited to indoor uses.

Recommended Mitigation Measures and Labeling Requirements

The following labeling requirements must be incorporated into all labels for all manufacturing and end-use products.

a. Manufacturing-Use Products

"This pesticide is toxic to birds, fish, and aquatic invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public waters unless this product is specifically identified and addressed in an NPDES permit. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA."

b. End-use Products

"This product is toxic to birds, fish, and aquatic invertebrates. Do not apply directly to water. Do not contaminate water when disposing of equipment washwater or rinsate."

Since all labels submitted to the EFED indicate that all products containing propetamphos are limited to indoor uses, few mitigation measuring and labeling requirements are recommended. Possible clarifications on labels include the following.

a. Under the **General Information** section the labels state "**FOR INDOOR USE ONLY.** Permitted sites of application include but are not limited to homes, apartment building, stores, warehouses (including food warehouses where items are limited to bottled, canned, and boxed items), schools, nursing homes, hospitals, and industrial buildings." The phrase "and other indoor structures" should be added to the end of the sentence. In addition, the phrase "but not limited to" should be deleted.

C. ENVIRONMENTAL RISK ASSESSMENT

1. Use Characterization/ Profile - Propetamphos

a. Type of Use: Acaricide-Insecticide

b. **Use Site:** Indoor Food, Indoor Non-food, Indoor Medical, Indoor residential

c. **Target Pests:** Ants, Boxelder Bug, Brown Dog Tick, Carpenter ants, Carpet beetle, Cockroaches, Confused flour beetle, Crickets, Earwigs, Firebrat, Fleas, Ground beetles, Pillbugs, Red Flour Beetle, Sawtoothed Grain Beetle, Silverfish, Sowbugs, Spiders

d. **Formulation Type:**

I. Technical Grade Active Ingredient

Formulation not identified. Active ingredient = 90%. Inert ingredients = 10%.

ii. **End Use Products**

Emulsifiable concentrates. Active ingredients = 18.9, 46.5, and 50.0%

Pressurized Liquid. Active ingredient = 1.0%.

e. Method and Rate of Application:

I. **<u>Types of treatment</u>:**

Crack and crevice and/or spot treatment

ii. **<u>Equipment</u>:**

Aerosol can; Injection equipment; Sprayer

iii. **<u>Timing</u>:**

When needed

iv. <u>Estimated Annual Poundage</u>

The BEAD estimates that total annual usage ranges from a low of **xxxxxxxxx** ai to a high of **xxxx**. It is believed that about **xxxxx** of this total poundage is used for control of roaches and fleas.

2. Exposure Characterization

a. Environmental Fate Assessment

The EFED has extremely limited data on the chemical propetamphos as the uses are limited to indoor use only. Generally, for indoor use chemicals, only hydrolysis data are required. The available data indicate propetamphos is stable to hydrolysis at neutral pH and hydrolyses under acidic (pH 3) and alkaline (pH 9) conditions slowly with half-lives of 11 and 41 days respectively. Propetamphos is soluble in most organic solvents, has a water solubility of 110 ppm at 24^{o}C and has a boiling point of 0.005 mm Hg at 87-89 C.

b. Environmental Fate and Transport Data

Due to the use of propetamphos being limited to indoor use only, environmental exposure is considered to be negligible. Due to the indoor use, only hydrolysis data are required which are summarized below.

I. Degradation

-Hydrolysis (161-1). (Acc. No. 250621, 1979) Results indicate that propetamphos is stable to hydrolysis at pH 6 and 25^{o} with a half-life of 365 days. Propetamphos hydrolyzes slowly in acidic (pH 3) and in alkaline solutions (pH 9) with half-lives of 11 days and 41 days, respectively. At pH 7 the half-life was 17 days in solution maintained at an elevated temperature of 45^{o}C. Thus, hydrolysis would be considered to occur slowly at pH 7 at 25^{o}C, with a half-life between 41 and 365 days. Isopropyl acetoacetate was an intermediate degradation product which further degraded to isopropanol, acetone, and carbon dioxide.

c. Water Resource Assessment

Due to the use of propetamphos being limited to indoor use only, environmental exposure is considered to be negligible.

d. Terrestrial Exposure Assessment

Due to the use of propetamphos being limited to indoor only, environmental exposure is considered to be negligible.

3. Ecological Effects Characterization

a. Terrestrial Hazard Assessment

Because all currently registered products of Propetamphos are limited to indoor uses, little exposure to nontarget terrestrial organisms is expected. To establish toxicity levels the EFED requires acute testing of an avian species, preferably the bobwhite quail. The required tests include an acute oral LD50 and a dietary LC50. This limited data set is sufficent because little exposure is expected to nontarget organisms.

b. Toxicity to Terrestrial Animals

I. Birds - An acute oral toxicity study using the technical grade of the active ingredient (TGAI) is required to establish the acute oral toxicity of Propetamphos to birds. The preferred test species is the bobwhite quail (an upland gamebird) for indoor uses. The test species used for propetamphos was the mallard duck. Results of this test are tabulated below.

Avian Acute Oral Toxicity

Species	% ai	LD50 (mg/kg)	Toxicity Category	MRID No. Author/Year	Study Classification[1]
Mallard duck *(Anas platyrhynchos)*	92	197	Moderately toxic	Acc. #: 235623, Beavers, J.B., 1978	Core

[1] Core (study satisfies guideline). Supplemental (study is scientifically sound, but does not satisfy guideline)

Since the LD50 falls in the range of 197 mg/kg, Propetamphos is categorized moderately toxic to avian species on an acute oral basis. The guideline (71-1(a)) is fulfilled (MRID 235623).

One subacute dietary study using the TGAI are required to establish the dietary toxicity of Propetamphos to birds. The preferred test species are mallard duck or bobwhite quail. Results of these tests are tabulated below.

Avian Subacute Dietary Toxicity

Species	% ai	5-Day LC50 (ppm)[1]	Toxicity Category	MRID No. Author/Year	Study Classification
Northern bobwhite quail *(Colinus virginianus)*	91	258	highly toxic	Acc # 241418, Beavers, J.B. & Fink, R., 1979	core
Mallard duck *(Anas platyrhynchos)*	91	>1780	Slightly toxic	Acc # 241418, Beavers, J.B. & Fink, R., 1979	Supplemental[2]

[1] Test organisms observed an additional three days while on untreated feed.

[2] An LC50 > 5000 ppm could not be determined because the highest dose tested was 1780 ppm. Study will not need to be repeated because the Northern bobwhite quail was more sensitive.

Since the LC50 falls in the range of 258 to >1780 ppm, Propetamphos is categorized as highly toxic to avian species on a subacute dietary basis. The guideline (71-2 (a) is fulfilled (MRID 241418).

No additional terrestrial ecological toxicity testing is required because propetamphos registered uses are limited to indoor sites.

c. Aquatic Hazard Assessment

Because all currently registered products of Propetamphos are limited to indoor uses, little exposure from spray drift or run-off to aquatic ecosystems is expected. For this reason, the EFED does not conduct a hazard assessment or risk characterization. To establish toxicity levels for aquatic species, the EFED requires acute testing of a freshwater fish species and a freshwater aquatic invertebrate. The preferred test species for freshwater fish is the rainbow trout. The test species for freshwater aquatic invertebrates is the water flea (*Daphnia magna)*. The required tests are LC50s. This limited data set is required because little exposure is expected to aquatic nontarget organisms.

d. Toxicity to Aquatic Organisms

I. Freshwater Fish - One freshwater fish toxicity study using the TGAI is required to establish the toxicity of Propetamphos to fish to support indoor uses. The preferred test species is the rainbow trout (a coldwater fish), however, data have been submitted for the bluegill sunfish (a warmwater fish) as well. Results of these tests are tabulated below.

Freshwater Fish Acute Toxicity

Species/ Flow-through or Static	% ai	96-hour LC50 (ppb) (measured)	Toxicity Category	MRID No. Author/Year	Study Classification
Rainbow trout *(Oncorhynchus mykiss)* static	91	1000	Highly toxic	Acc #: 241418, Seminra, J.,1979	Supplemental
Rainbow trout *(Oncorhynchus mykiss)* static	90	2600	Moderately toxic	416074-15, Bowman, Jane, 1990.	Core
Bluegill sunfish *(Lepomis macrochirus)*	90	1100	Moderately toxic	416074-09, Bowman, Jane, 1990.	Core
Bluegill sunfish *(Lepomis macrochirus)*	91	188	Highly toxic	Acc #: 241418, Seminra, J.,1979	Core

Since the LC50 falls in the range of 188 to 2600 ppb, Propetamphos is categorized as moderately to highly toxic to freshwater fish on an acute basis. The guideline (72-1) is fulfilled. (MRID #s 416074-15 & 416074-09 & Acc. #s 241418)

All registered products of Propetamphos are currently limited to indoor uses, and as such, freshwater fish chronic is not required.

ii. Freshwater Invertebrates - The minimum testing required to establish the toxicity of a all registered products limited to indoor uses to freshwater invertebrates is a freshwater aquatic invertebrate toxicity test, preferably using first instar *Daphnia magna* or early instar amphipods, stoneflies, mayflies, or midges.

A freshwater aquatic invertebrate toxicity test using the TGAI is required to establish the toxicity of Propetamphos to aquatic invertebrates. The preferred test species is *Daphnia magna*. Results of this test are tabulated below.

Freshwater Invertebrate Acute Toxicity

Species/Static or Flow-through	% ai	48-hour LC50/ EC50 (ppb) (measured)	Toxicity Category	MRID No. Author/Year	Study Classification
Waterflea *(Daphnia magna)*	90	3.3	Very highly toxic	416074-01, Burgess, David, 1990	Core
Waterflea *(Daphnia magna)*	92	14.47	Very highly toxic	Acc #: 235623, Morrissey, A.E.	Core

Since the LC50/EC50 falls in the range of 3.3 -14.5 ppb, Propetamphos is categorized as very highly toxic to aquatic invertebrates on an acute basis. The guideline (72-2) is fulfilled (MRID # 416074-01 & Acc. # 235623).

Since all registered products of Propetamphos are currently limited to indoor uses, little exposure to aquatic ecosystems is expected. **Therefore, a freshwater chronic invertebrate life-cycle test is not required.**

Freshwater field studies will not be required for Propetamphos because all registered products are currently limited indoor uses, and little exposure to aquatic ecosystems is expected.

iii. Toxicity to Estuarine and Marine Animals - As mentioned above, since all registered products of Propetamphos are currently limited to indoor uses, marine/estuarine testing is not required.

iv. Aquatic Plants - Aquatic plant testing is not required for Propetamphos because all currently registered products of Propetamphos are limited to indoor uses and little exposure to nontarget plants is expected.

4. Environmental Risk Characterization

Since all registered products of Propetamphos are currently limited to indoor uses, an environmental risk characterization is not required.

5. Labeling Requirements

The following labeling requirements must be incorporated into all labels for all manufacturing and end-use products.

a. Manufacturing-Use Products

"This pesticide is toxic to birds, fish, and aquatic invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public waters unless this product is specifically identified and addressed in an NPDES permit. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA."

b. End-use Products

"This product is toxic to wildlife and aquatic invertebrates. Do not apply directly to water. Do not contaminate water when disposing of equipment washwater or rinsate.."